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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
KOSAR, AARON J	

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
02/12/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No.	Applicant(s)	
	10/516,307	KIKUCHI ET AL.	
	Examiner	Art Unit	
	AARON J. KOSAR	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *43-59* is/are pending in the application.

4a) Of the above claim(s) *43-59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/09/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 9, 2008 has been entered.

Applicant's amendment and arguments filed October 9, 2008, are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

Applicant has amended the claims by canceling claims 1, 4-6, 13-26, and 29 and introducing new claims 54-59. **Claims 43-59** are pending and have been examined on the merits.

Information Disclosure Statement

The information disclosure statement (IDS) filed on October 9, 2008 does not fully comply with the requirements of 37 CFR 1.98(b) because: "Brix" (**AW**:IDS) does not comply with the format of internet references (including reciting a pagination of "3 pages"). See MPEP §707.05(e)(IV), especially examples 5-11, and for example US 7,487,283.

For the sake of compact prosecution the reference has been considered and the corrected reference relisted on the IDS as reference (**AX**).

Claim Objections

In view of Applicant's arguments and objective evidence made of record the unit of measure of R-Bx is afforded the meaning in the art of the *refractometric brix* (i.e. degree brix (^{0}Bx) measured refractrometrically) as evidenced by BRIX (**AX**:IDS page 2).

Claims 43 and 59 are/remain objected to because of the following informalities:

In claim 43, the phrases "purity of at least.. w/w % based on dry weight", "purity of at least..w/w%" , "purity of less than 70%", and "purity of at 70 w/w% or more based on dry weight.." are objected to because the terms are internally inconsistent in the usage of the unit of measure; however, this objection may be overcome, for example, by reciting: "purity based on dry weight of at least 70%(w/w)", "a purity based on dry weight of less than 70%(w/w) and of at least 60%(w/w)", and "purity based on dry weight of 70%(w/w) or more".

In claim 43, line 2, and claim 54, line 1, the quotation marks should be removed from the term -- difructose dianhydride III (DFA III) --.

In claim 59 the dependent claim introducing an additional step to the method of claim 54 should recite "further comprising".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 43-59 are/remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "DFA III-containing solution containing DFA III at a purity of…70 w/w% based on dry weight" and "based on dry weight" are unclear because the unit of measure "w/w%" is afforded the common meaning in the art of *g partial component A per 100g component/composition B*. In the instant case it is unclear how DFA III, the solution, a dry composition from the solution comprising DFA III, or other components correspond to the "w/w%" unit numerator (A) and denominator (B) contributions; and thus the object(s) for which "based on dry weight" correlates is also unclear, and it is unclear which combination Applicant intends to embrace by the phrases.

The phrase "the DFA III containing solution" in claim 43, line 3 is unclear because the phrase lacks sufficient antecedent basis in the claim as the claim does not recite providing "a DFA III containing solution".

In claim 43, line 9 and claim 54, line 7, the term "solid phase…of the solution" of the solution containing "carbon particles" is inconsistent with the usual meaning of a "solution". It is unclear if the carbon-and-solution combination provides for a solution (dissolved carbon) or a composition comprising carbon and a solution. The claim has been examined to the extent of a carbon-and-solution composition (e.g. a suspension) for the sake of compact prosecution; however, this does not absolve Applicant of the requirement to appropriately amend the claims as the specification does not clearly and unambiguously redefine the term "solution" to embrace suspensions.

Claims 43-59 are rejected as being incomplete for omitting essential steps.

While all of the technical details of a method need not be recited, the claims should include enough information to clearly and accurately describe the invention and how it is to be

practiced. The minimum requirements for method steps minimally include a *providing/contacting step* in which the reaction of the sample with the reagents necessary for the assay is recited, a *reacting/detecting step* in which the reaction steps are quantified or visualized, and a *concluding/correlating step* describing how the results of the assay allow for the determination.

In these claims, the *providing* and *correlating steps* are missing, because the claim preamble is drawn to a process of "purifying DFA III having a purity of at least 70 w/w%" whereas the active steps are not commensurate with the method. The method steps as instantly claimed require instead, *providing* a DFA III having a purity less than 70 w/w% (and greater than or equal to 60% w/w%) and recovering a DFA III having a purity of 70 w/w% or more. Please note, however this ground may be overcome by amending the preamble or active steps to recite a method correlated to the active steps extending therefrom.

For the sake of compact prosecution the claims have been examined to the extent of the active method steps; however, this does not absolve Applicant of the requirement to appropriately amend the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 43, 45, 47-55, and 57-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over TANAKA (**AP, N'** of record) *or* UCHIYAMA (**A**, of record) *or* TOMITA (**N**), *and* in view of SAITO (**V"**:PTO-892: Katsuichi Saito and Fusao Tomita "Difructose Anhydrides: Their Mass-Production and Physiological Functions" Biosci. Biotechnol. Biochem. 2000, 64(7), 1321-1327.) *and* ARMAREGO (**U'**, of record.)

The claims are generally drawn to a method of purifying (i) a DFA III composition to provide (ii) a purified DFI III comprising contacting (i) with activated carbon, phase separation, and recovery of DFA III. The claims are also in general further drawn to percentages, relative quantities, and dimensions of the components.

TANAKA (AP,N') teaches the DFA product in solution (500 ml extract); less than 70% pure (0.5g DFA recoverable per 500 ml extract); the use of yeast, including fermenting with the aerobe *A. ureafaciens*; defecation (filtering boiled/sliced burdock); adsorption onto active carbon; filtering to separate the solid carbon adsorbate from the liquid filtrate; and chromatographing with HIGH-FLOW SUPERCELL (eluted with 5% ethanol) in the purification of the difructose dianhydride product (English abstract; English translation: page 4, ¶1-2; page 5 ¶1 and 3).

UCHIYAMA (A) teaches a process for preparing DFA III comprising obtaining DFA via a centrifuged *Arthrobacter ilicus* cell-filtrate; adjusting the filtrate concentration (from 150mL to 10mL) under reduced pressure; passing the filtrate through and further purifying the DFA III-containing fraction by an activated carbon/CELITE column, and finally concentrating to dryness the eluted peaks to yield purified DFA III. Uchiyama also teaches that the inulin-lytic enzyme may be provided as the enzyme *per se* (an extract) or in the form of the obligate aerobe microorganism producing the enzyme (e.g. column 5, lines 4-7) and that inulin may be obtained from a variety of sources.

TOMITA (N) teaches a method for purifying DFA III (Derwent- English abstract). Tomita teaches purification using centrifugation to defecate the suspended particles, and filtering by passage through activated carbon and silicates (i.e. CELITE) (Derwent- English abstract, lines

7-9). Tomita also teaches a purity of DFA III of less than 70% in that Tomita teaches a composition comprising 95% components other than inulin. Thus even 100% conversion of inulin to DFA III by the inulinase would produce a composition comprising no more than 5% DFA III. Tomita also teaches action of a fructosyltransferase upon a fructose/fructose-containing polymer by teaching the reaction of inulinase upon inulin to produce DFA III (Derwent- English abstract, line 1).

SAITO (V") teaches mass production of DFA III from a variety of DFA III-producing organisms (table 1). Saito also teaches the benefit of purifying inulin from chicory (§1) and purifying DFA III with microorganisms producing inulase II (EC 2.4.1.93) including *Arthrobacter* sp H65-7, wherein DFA III is produced in a yield (purity) of 93% (page 1323, ¶(1); table 2). The purified composition is further purified, including by depleting the composition of fructose and liner oligosaccharides by yeast treatment (1323, §(1), ¶3).

ARMAREGO (U') teaches that "purity is a matter of degree" and that absolute purity is an unattainable ideal (page 1, ¶1). Armarego teaches that carbon (charcoal/decolorizing carbon) is useful in the removal extraneous/contaminant material for solutions by the addition of a small amount of carbon to a solution, then filtered, and that a "greater degree of purity is also to be expected if the [crystallization] process is repeated several times" (page 12, "Recrystallization: Techniques", ¶2). Armarego further teaches that purification by filtration may be supplemented with filter aids, including the diatomaceous earth/silicates "CELITE, FLORISIL, or HYFLO-SUPERCEL" or substituted with various porosity filters (filter paper, glass fibre, sintered glass, NYLON, TEFLON, polyvinyl chloride filters, etc.) or centrifuged depending on the solvent and the nature of compounds in solution/suspension (e.g. particle size, (in)solubility)(page 13). Still

further, Armarego teaches that purification of complex organic mixtures includes adsorption chromatography, wherein the adsorbents include "charcoal (usually mixed with kieselgurh or other form of diatomaceous earth, for example, the filter aid CELITE)" (e.g. "Graded Adsorbents and Solvents", page 18).

TANAKA differs from the instant claims in that Tanaka appears to be silent with respect to the percentage purity and brix of the starting material and product; the quantity and quality (particle size/surface area/mesh) of carbon adsorbent used; and the sequence of contacting of the solid, liquid, and carbon.

UCHIYAMA differs from the instant claim in that Uchiyama appears to be silent with respect to the claimed percentages, amounts, and dimensions of the carbon and DFA compositions.

TOMITA differs from the instant claims in that Tomita appears to be silent with respect to the claimed purity of DFA, percentage of carbon.

It would have been obvious to use any active carbon source or any DFA III and to purify the composition to the desired purity in the methods of TANAKA/UCHIYAMA/TOMITA, because SAITO teaches that DFA III isolated from a variety of sources was known at the time of the invention and because ARMAREGO teaches that purity is merely a matter of degree whereby a variety of techniques are well-established and routinely optimized for the purpose of purification, including filtration/adsorption with silicates (e.g. diatomaceous/Fuller's earth), silica, activated carbon, etc.

One would have been motivated to purify the compositions with active carbon, because TANAKA/UCHIYAMA teach in general that DFA may be purified using active carbon and HIGH-FLOW SUPERCELL/CELITE. The quality (purity, brix) of the DFA of Tanaka appears to be an obvious variant of that instantly claimed in that the compositions appear to have the same chemical core, obtained from the same composition (and/or commercially available materials), and would thus be expected to have similar chromatographic selectivity properties, especially as said purification relates not to the DFA but to the adsorption of the impurities therewith. Additionally, the type and amount of active carbon used also appears to be an obvious variant of the instantly claimed activated carbon in that both materials comprise active carbon and are useful for the same purpose intrinsic to activated carbon (purification, decolorizing, deodorizing, etc.). Thus the contacting of each of the starting material DFA and the carbon of any size, purity, or quantity would still be expected to interact in the manner claimed (increasing the purity of the composition), especially in the absence of criticality or objective evidence to the contrary.

One would have had a reasonable expectation of success in making a purified DFA III composition, because the success depends upon contacting a DFA composition of known core structure, with activated carbon of known activity, in a known method (contacting/adsorbing), to yield a predictable result (increased purity/ removal of adsorbed impurities) and well within the purview of the skilled artisan.

Tanaka and Saito are relied upon for the reasons discussed above. If not expressly taught by Tanaka/Saito, based upon the overall beneficial teaching provided by this reference with respect culturing an aerobic bacteria, extent of purification of reagents/products, and proportions

of ingredients in the manner disclosed therein, the adjustments of particular conventional working conditions (e.g., determining one or more suitable concentration ranges (e.g. aerobe culturing oxygenation/aeration; quantities, qualities, and proportions of composition components in which to perform such a purification), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Furthermore, selection of any order of mixing ingredient is *prima facie* obvious in the absence of new or unexpected results (see, e.g., *In re Gibson*, 5 USPQ 230 - CCPA 1930). MPEP § 2144.04. Also, Selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results (see, e.g., *Ex parte Rubin*, 128 USPQ 440, 1959, and *In re Burhans*, 154 F.2d 690, 69 USPQ 330 - CCPA 1946) MPEP § 2144.04.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Please note, claims 50-52 have been included in this rejection since the treating of inulin does not require an isolated, purified, or other manipulation which would distinguish an inulin conversion by an organism containing the enzyme from inulin conversion by an (inulin) fructosyltransferase enzyme *per se*.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the

forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments filed October 9, 2008 are acknowledged. Applicant has in general argued that the prior art (AP/N'/A/N in view of U) does not provide for a reasonable expectation of success. Applicant also argues that the prior art does not teach the components having the claimed purity (<70%), size (15-200μm), or concentration (w/w%); that the instant process differs in providing for selective removal of non-DFA III impurities by contacting with active carbon particles in the requisite range (5% (w/w) or less). Applicant's arguments have been fully considered; however, respectfully they are found to be not persuasive.

Regarding the reasonable expectation of success, for the reasons of record, success to the extent claimed merely requires contacting with activated carbon, for the intended purpose/intrinsic function of said carbon, as an adsorbent, wherein the adsorption is known in the art as a means of decolorizing deodorizing impure compositions (**A**":PTO-892: LI, US 2002/0158001 A1, page 1, ¶4). Furthermore, success minimally requires a single molecule be purified/removed from the composition, wherein 5 w/w% activated carbon versus 1 molecule provides for a significant excess of carbon relative to said molecule (*i.e.* >60 to <70 w/w%

versus ≥70w/w% corresponds to a range of purification = 1 molecule to <10 w/w%). Thus to the extent the prior art teaches removal of other components than DFA III (or the separation of DFA III from other components) the compositions of the prior art appear to meet the claims. The motivation to purify is provided by the prior art for the reasons of record, including Amarego which teaches that all compositions are necessarily impure and by the teachings that activated carbon functions as a filtering adsorbent, decolorizing and deodorizing impure compounds contacted therewith. Thus, for the reasons of record, the prior art teaches the motivation for purification *and* the reasonable expectation of success in providing the known and predictable a method and product therefrom to the extent claimed, especially in the absence of objective evidence to the contrary or objective evidence to the criticality of a particular range upon the functioning of activate carbon and DFA III in the expected manner.

To the extent that Applicant's arguments may rely upon a particular concentration or scale of reaction, for the reasons of record it would have been obvious to have routinely optimized the reaction and/or a matter of judicious selection which is well within the purview of the skilled artisan, especially absent objective evidence to the criticality of the range upon the chemical interaction between DFA III and activated carbon, to the extent claimed.

In response to applicant's arguments that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., colored, odorous, and/or impurity component(s)) are not positively-recited in the rejected claim(s) and in view of Amarego's teaching that absolute purity is an impossible ideal, absent the mode of measurement/detection and the threshold level a composition is deemed to be colorless/odorless, the compositions of the prior art are still deemed to embrace the compositions of the method to

the extent claimed. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Please note, since the Office does not have the facilities for examining and comparing Applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed composition produced by the method and the product(s) of the prior art. *See In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980), and "as a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:
KIKUCHI (U":PTO-892: Hiroto Kikuchi, et al. "Physical, Chemical and Physiological Properties of Difructose Anhydride III Produced from Inulin by Enzymatic Reaction." Journal of Applied Glycoscience (2004), 51(4), 291-296.) *teaches producing "high purity difructose anhydride III (DFA III...) crystals from the crude inulin extracted from chicory with inulin fructotransferase (depolymerizing) induced by H65-7 strain of Arthrobacter sp."; chicory juice containing 15 kg inulin providing for 9.8 kg DFA III in the reaction mixture and for 3.0 kg of the refined (yeast fermented, ion-exchanged, and crystallized) product (page 291). Kikuchi also teaches that "coloring [of DFA III or sucrose] by the Maillard reaction was measured at 420nm"(abstract; page 292, ¶ (10)) appears to be*

the NPL disclosure of the instant invention and relevant to the general state of the art at the time of the instant invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. KOSAR whose telephone number is (571)270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday,EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ajk/
Aaron Kosar
Examiner, Art Unit 1651

/Sandra Saucier/

Primary Examiner, Art Unit 1651